ATTACHMENT D

Results-Based Accountability

Assessment of

Regulation of Hearing Instrument Specialists

Prepared By

Legislative Program Review and Investigations Committee
Per C.G.S. Sec. 2c-4

February 22, 2012

Committee Staff on Project
Miriam P. Kluger, Principal Analyst

Legislative Program Review and Investigations Committee
Connecticut General Assembly
State Capitol Room 506
Hartford, CT 06106
(860) 240-0300 Email: pri@cga.ct.gov Web: www.cga.ct.gov/pri/index.htm

RESULTS-BASED ACCOUNTABILITY FRAMEWORK: REGULATION OF HEALTH PROFESSIONALS

POPULATION LEVEL ACCOUNTABILITY

QUALITY OF LIFE RESULTS STATEMENT:

"All Connecticut residents experience good physical, mental and economic health, safety and welfare through the regulation of health professionals."

KEY INDICATORS of Progress Toward Population Level Results

Indicator 1: **Physical health and safety** *Percent of time clients unharmed by a licensed professional*	Indicator 2: **Emotional well-being** *Rate with which consumers are treated fairly and with dignity*	Indicator 3: **Economic welfare** *Percent of time clients have trouble-free financial transactions with licensed professional*

PARTNERS CONTRIBUTING TO RESULTS STATEMENT

CT General Assembly Congress Governor State Agencies: DPH, DCP, OAG Municipalities	Federal Agencies: FDA, FTC, OSHA Boards and Commissions Medical personnel and other Professionals/Practitioners Better Business Bureau Advocacy groups	Educational and Health Care Institutions Businesses Colleges, training institutions producing professionals Professional associations

MAIN STATE STRATEGIES FOR ACHIEVING RESULTS STATEMENT

Ensure minimum level of compliance with licensure and regulations	Ensure safe and sanitary conditions at regulated facilities and businesses	Enforce fair and honest financial practices	Investigate and resolve complaints

AGENCY AND PROGRAM LEVEL ACCOUNTABILITY

AGENCY AND BOARD CONTRIBUTIONS TO RESULTS STATEMENT: MAIN ROLES AND RELATED MAJOR PROGRAMS

Set and apply standards for trained and competent practitioners	Protect public from the spread of disease, risk and physical injury by licensed professionals	Safeguard the public from negligent and unscrupulous professional practices	Protect public from economic harm by professionals in the field	Establish and implement processing for complaints about services received by the professional
• DPH license processing and setting standards	• DPH facilities inspections • DPH licensing examinations • DPH continuing education requirements	• DPH complaint investigation • DPH/board hearing process and sanctioning	• DCP investigation of unscrupulous business practices • DPH sanctioning of licensed individuals	• DPH complaint receipt and investigation • DPH/board hearing process and sanctioning

PROGRAM LEVEL PERFORMANCE MEASURES: REGULATION OF PROFESSIONS

- DPH and any associated Boards are in full compliance with relevant statutory and regulatory requirements
- Efforts are made to prevent and detect any negative impact on the physical health of consumers caused by the actions of the licensed professionals
- Unscrupulous practitioners are removed or monitored to limit further complaints
- Efforts are made to prevent, detect, and resolve financial fraud or dishonesty
- All complaints regarding deceptive practices are successfully resolved

RBA Program Performance Report Card:
Regulation of Hearing Instrument Specialists

Contributes to the Quality of Life Results Statement:

All Connecticut residents experience good physical, mental and economic health, safety and welfare through the regulation of health professionals.

Main Contribution: The regulation of hearing instrument specialists helps protect public health by having practitioners who are competent and will not further hearing loss or other physical harm through improper fitting of hearing aids, safeguard emotional well-being by ensuring that clients are treated with fairness and dignity, and economic welfare through enforcement of fair and honest financial practices.

Program Background

- Licensure of persons both fitting and selling hearing aids was initiated in 1972, and changed in 1977 to licensure for persons either fitting or selling hearing aids.
- Over the years, consumer protections were added including requirements for 30-day trial periods, refunds and cancellation policies, and required written sales receipts.
- Terminology changed from "hearing aid dealers" to "hearing instrument specialists" in 1999.

Regulation of Hearing Instrument Specialists Performance Summary

Five key measures of performance for public health-related regulation are highlighted below, followed by separate discussions of two areas—licensure, and complaints and violations. Within each, two of the three RBA program performance questions--How much did we do? And How well did we do it?—are answered. The final section answers the key, third question: Is anyone better off?

Key Measures	Status	Current Data
1. DPH is in full compliance with relevant statutory and regulatory requirements	+	• DPH has complied with all statutory and regulatory requirements to license, investigate and sanction hearing instrument specialists: o 122 licensed hearing instrument specialists were licensed in 2010. o three complaints against hearing instrument specialists were received in 2009, and all three were investigated by DPH. • Although audiology licensure requires greater educational and training requirements and the state statute on the practice of audiology includes the fitting and selling of hearing aids, the current hearing instrument specialist statute requires audiologists to either obtain a hearing instrument specialist license, provide DPH with documentation showing certain coursework and supervised clinical experience, or pass the written exam required for a hearing instrument specialist license. o PRI staff recommends this additional requirement be eliminated as it is unnecessary and potentially burdensome for both the audiologists and DPH.

2. Efforts are made to prevent and detect any negative impact on the physical health of consumers caused by the actions of the licensed professionals	+	• Hearing aids are classified as medical devices by the FDA who notes, if the hearing aid is not properly fitted, then too much amplification may cause additional hearing loss • Unlike many other states, continuing education is not required to renew the hearing instrument specialist license in Connecticut. Given the highly technical and rapidly changing nature of the field, PRI staff recommends adoption of continuing education requirements.
3. Unscrupulous practitioners are removed or monitored to limit further complaints	?	• Due to DPH actions, two incompetent and negligent/unscrupulous hearing instrument specialists have been sanctioned during the past 10 years • Limited information is known about complaints received by the Better Business Bureau (BBB) rather than DPH regarding hearing instrument specialists.
4. Efforts are made to prevent, detect, and resolve financial fraud or dishonesty	+	• Hearing instrument specialists are required to provide a 30-day trial period in the purchase of a hearing aid • Hearing instrument specialists are required to provide the consumer with a written sales receipt showing the 30-day trial period • DPH has received very few complaints involving potentially fraudulent or deceptive practices
5. All complaints regarding deceptive practices are successfully resolved	+	• All DPH-processed complaints may be investigated or dismissed. In FY 10, for example: o three of the three complaints received (100%) were investigated o two of the three complaints were subsequently dismissed with no action taken o one complaint resulted in sanctioning the licensee to one year of probation and successful completion of a DPH-approved course in documentation standards • The median amount of time it took to process hearing instrument specialist complaints was six months, with investigations ranging from 3-13 months. • Consumers complaining to the BBB about a hearing instrument specialist, may not be aware that only DPH can sanction hearing instrument specialists

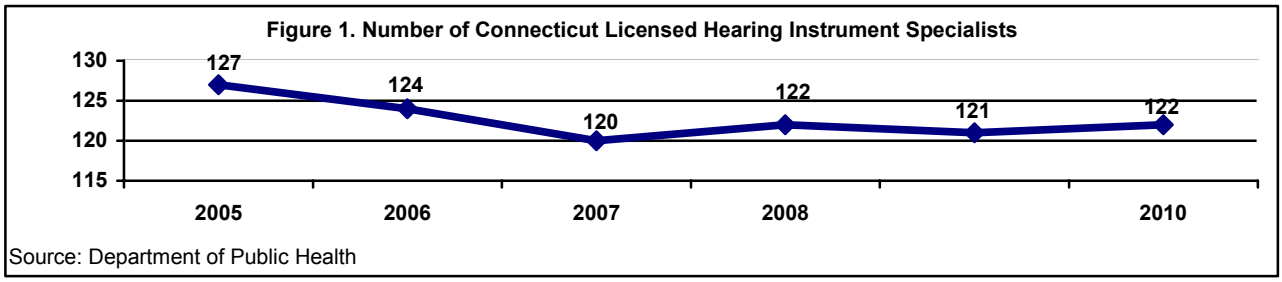
LICENSURE

In 2010, the Department of Public Health oversaw the licensure of hearing instrument specialists including holding licensing exams.

I. HOW *MUCH* DID WE DO?

Performance Measure 1: Number of Licenses Issued

- DPH licensed 122 hearing instrument specialists in 2010 (Figure 1).
- There were 17 applications for new hearing instrument specialist licenses in FY 10.



Performance Measure 2: Number of Licensure Exams Held Annually

- By statute, DPH is required to hold licensure exams for hearing instrument specialists at least twice per year.
- On a regular basis, DPH offers required licensure exams twice per year.

II. HOW *WELL* DID WE DO IT?

Performance Measure 3: Percent of Trained and Competent Applicants Who Received Licenses

- Hearing instrument specialist licenses are only granted to applicants who have successfully completed the education, supervised work experience/apprenticeship, and examination requirements.
- In FY 09, 100% of the nine hearing instrument specialist applicants met the hearing instrument specialist licensing requirements and were licensed.

Performance Measure 4: Presence of Requirements for Audiologists Wishing to Fit and Dispense Hearing Aids

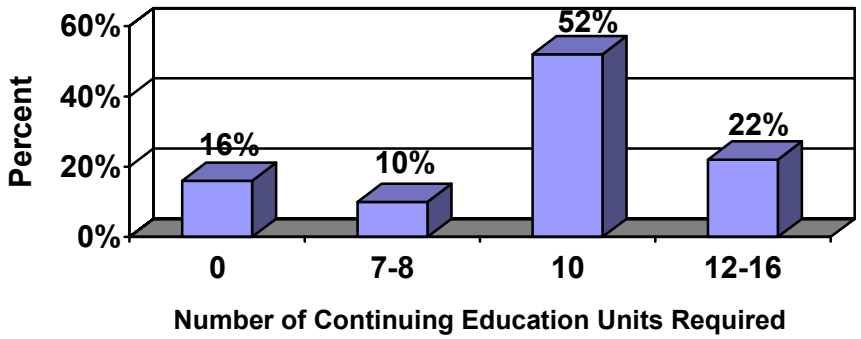
- Almost all audiologists fit and dispense hearing aids.
- Audiologists must meet two sets of requirements to fit and dispense hearing aids:
    - licensure as an audiologist; and
    - one of the following:
        - obtain a hearing instrument specialist license;

- provide DPH with documentation showing satisfactory completion of relevant coursework and supervised clinical experience; or
- pass the written exam required for a hearing instrument specialist license.

Performance Measure 5: Presence of a Requirement for Continuing Education

- Continuing education is intended to ensure that practitioners maintain competency and keep up-to-date and knowledgeable about changes in their profession's field.
- Continuing education is not required to renew the hearing instrument specialist license.
- Many states require continuing education as a condition of licensure renewal (Figure 2) including the New England states of Maine and New Hampshire.

Figure 2. Annual Number of Continuing Education Units Required



Performance Measure 6: DPH Application Processing Time

- On average, in 2010, it took 6-9 months for new applicants to become licensed.
- DPH reported the licensing process was conducted in a timely manner.
- Processing time depended primarily on when education, supervised work experience/apprenticeship and exam requirements were completed by the applicant.

Story Behind the Data

Hearing instrument specialists are regulated in all 50 states, most often through licensure (92 percent of the time). There have been a relatively steady number of licensed hearing instrument specialists during the past five years.

Data on the numbers of licensed personnel and facilities are reported annually in DPH's publication, "Total Active Licenses." To assess trends, data from each year's separate report must be compiled manually.

DPH met the minimum statutory requirement of offering exams to hearing instrument specialists twice a year. Applicants also have the option of obtaining an apprentice permit prior to passage of the licensing exam, allowing them to practice under the direct supervision of a licensed hearing instrument specialist for up to two years while completing additional training and awaiting exams.

Because all applicants had met the requirements for licensure, it is likely that the requirements are easily accessible and made clear to those interested in becoming licensed. Further, the amount of time it took to process hearing instrument specialist licenses in Connecticut is similar to the Massachusetts statutorily-required eight month median processing time for hearing aid dispenser licensure applications.[1]

Given that it is a rapidly changing field, and national board certification and the majority of states have such a requirement, Connecticut's residents may be better protected and served by having a continuing education requirement for hearing instrument specialist licensure renewal.

Although their educational requirements are much greater,[2] audiologists must at the very least, submit paperwork to DPH showing they received training in fitting and dispensing hearing aids (which all of them have received as part of their doctoral training). This paperwork is potentially burdensome for both the audiologists and DPH.

Actions to Turn the Curve

To improve the ease of acquiring (and therefore analyzing) multi-year data on licenses, **PRI staff recommends:**

> **DPH's report, "Total Active Licenses," be formatted to include data from each of the past five years.**

Given the highly technical and rapidly changing nature of this field, and consistent with current continuing education requirements to maintain national board certification, **PRI staff recommends:**

> **Hearing instrument specialists shall be required to complete 16 continuing education units prior to licensure renewal.**

To streamline unnecessary regulatory requirements, **PRI staff recommends**:

> **C.G.S. Sec. 20-398 shall be amended so that audiologists will not have to meet the additional hearing instrument specialist requirements in order to fit and dispense hearing aids.**

[1] M.G.L.A. Sec. 1399.113. Review of Hearing Aid Dispenser Applications; Processing Time.
[2] Prior to 2007, audiologists needed to earn a master's degree to be a licensed audiologist. Since 2007, audiologists must earn a doctorate in audiology and participate in a one-year externship following receipt of the doctoral degree.

COMPLAINTS AND VIOLATIONS

The public, professionals, and state agencies may register complaints against hearing instrument specialists with DPH. In the department's investigation of complaints, violations may be uncovered and sanctions imposed.

I. HOW *MUCH* DID WE DO?

Performance Measure 1: Number of Complaints Received by DPH

- DPH reports they investigate an average of two complaints per year against hearing instrument specialists.
- DPH received and investigated three complaints against hearing instrument specialists in 2009:
    - two complaints were dismissed with no action taken.
    - one complaint pertained to inadequate testing of a patient's hearing, and failure to adequately document the patient's treatment.

Performance Measure 2: Severity of Complaints Received by DPH

- Of four records reviewed by PRI staff for which this information was known, DPH staff classified the severity of complaints as follows: [3]
    - none (0%) at the highest priority level (Class 1);
    - two (50%) at the middle level (Class 2); and
    - two (50%) at the lowest level (Class 3).
- DPH staff report that complaints lodged with DPH against hearing instrument specialists generally do not demonstrate a serious or imminent risk to public health or safety.
    - Complaints tend to relate to unlicensed practice and/or payment/advertising issues.

Performance Measure 3: Number of Actions Taken by DPH Against Hearing Instrument Specialists

- DPH takes very few actions against hearing instrument specialists.
- One hearing instrument specialist was sanctioned through consent order in 2009 and:
    - received one year probation and was required to successfully complete a DPH-approved course in documentation standards.
- The next most recent consent order for a hearing instrument specialist occurred in 2005 and the respondent:
    - Was required to pay a civil fine of $500.

[3] Class 1 complaints require immediate action or response because the situation poses an immediate threat to public health and safety. Class 1 complaints include cases associated with patient death, practitioner impairment, sexual misconduct, or infection control issues. Class 2 complaints have direct or indirect impact on quality of care, quality of life, or public health and safety. Class 3 complaints appear to be violations of standards of practice, laws or regulations such as failure to release records, patient confidentiality, failure to complete physician profile, etc.

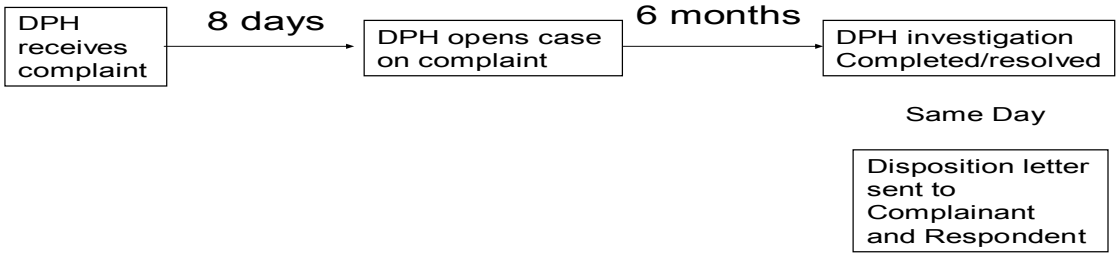
II. How *Well* Did We Do It?

Performance Measure 4: Timeliness of DPH Processing of Dismissed Complaints

- DPH guidelines state that Class 1 categorized investigations are to be "…completed as quickly as possible, but within ninety (90) days unless the PHSM [Public Health Services Manager] determines that an extended investigation is necessary and there is no threat to the public health and safety."
    - The department guidelines further state that the goal is to complete Class 2 and Class 3 investigations within 180 days.
- Overall, DPH does not retain records on complaint processing time for cases that are resolved by consent order; however, such information is retained for cases that are dismissed.
- For six complaints lodged during 2001-2006 and subsequently dismissed (i.e., did not receive a hearing or result in negotiated consent order):[4]
    - half the complaints were opened for DPH investigation within eight calendar days or less;
    - investigations ranged from three months to 13 months;[5] and
    - disposition letters were often sent to the complainant and respondent on the same day the complaint was resolved.

The process and median timeframes is shown in Figure 3.

Figure 3. Median Time for DPH to Process Dismissed Complaints



[4] DPH was unable to provide detailed information on timeframes for complaints that were resolved by consent order.
[5] Fraud and deception complaint brought by a patient.

Performance Measure 5: Percent of Consumers Understanding How to File a Complaint

- Information is not readily available on the percent of consumers understanding how to file a complaint.
- The DPH complaint form is online.
- There were at least as many complaints against hearing instrument specialists filed with the Better Business Bureau within the past three years as there were with DPH:
    - The Better Business Bureau website listed seven closed complaints against six businesses listed under "Hearing Aids & Assistive Devices."

Story Behind the Data

Because DPH does not monitor and report on complaint processing time by classification, it is difficult to asses whether complaints are investigated within the DPH guidelines for Class 1, 2, and 3 complaints.

DPH receives very few complaints about hearing instrument specialists. Limited information is known about complaints received by the BBB, and the BBB did not respond to PRI's request for additional information.

Colorado experienced an increase in complaints following de-regulation of hearing instrument specialists. That state's Attorney General Office, for example, found significant actual public harm by the unregulated practice of hearing aid sales based on investigation of 100 complaints in one year alone. The bulk of these complaints concerned failure to issue refunds, as well as cases of abuse of elderly clients, and outright fraud. Colorado subsequently re-regulated the profession through its department of health.

Action to Turn the Curve

To assess whether complaints are addressed in a timely fashion, **PRI staff recommends** that:

> **DPH should consider developing a system to monitor timeliness of complaint processing for all cases, with the ability to assess whether complaints are investigated within the DPH guidelines for Class 1, 2, and 3 complaints.**

III. IS ANYONE BETTER OFF?

Hearing instrument specialists are regulated in all 50 states, most often through licensure. Hearing aids are classified as medical devices by the FDA who notes, if the hearing aid is not properly fitted, then too much amplification may cause additional hearing loss. Consumers are better off dealing with trained and competent (i.e., licensed) hearing instrument specialists, with the vast majority of hearing aids and related services handled without complaint.

Performance Measure 1: Number of Negligent and Unscrupulous Practitioners Sanctioned

- Within the past 10 years, the following sanctions were imposed on two hearing instrument specialists:
    - 12 months probation and successful completion of a DPH-approved course in documentation standards (ordered for one hearing instrument specialist who failed to adequately test a patient's hearing, and adequately document the patient's treatment).
    - Civil penalty of $500 (ordered for one hearing instrument specialist who had allowed a temporary permittee to practice as a hearing instrument specialist without the presence of a licensed supervisor).

Story Behind the Data

There have been very few unscrupulous or negligent hearing instrument specialists that have come to the attention of DPH. However, without licensure (regulation), former hearing instrument specialists who are no longer licensed in Connecticut, or who lost their licenses in other states (due to revocation, voluntary surrender, etc.) would be able to re-enter the profession, and the public would no longer be protected from practitioners who had previously evidenced harm to the public.

However, hearing aids are classified as medical devices by the FDA.[6] The experience of Colorado following its de- regulation of hearing instrument specialists found significant actual public harm by the unregulated practice of hearing aid sales, and led to re-regulation of the profession.

Action to Turn the Curve

To maintain the level of regulation needed to protect the public health, safety, and welfare of Connecticut residents, **PRI staff recommends**:

The regulation at the licensure level of hearing instrument specialists should be continued.

[6] "Medical Devices: Benefits and Safety Issues" (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm181477.htm)